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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 558421C:RDC	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. **PCT/AU02/00974**	International Filing Date *(day/month/year)* 22 July 2002	Priority Date *(day/month/year)* 30 July 2001
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61M 1/12, F15B 3/00		
Applicant SUNSHINE HEART COMPANY PTY LTD et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of **3** sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[X]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[ ]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand 7 February 2003	Date of completion of the report 11 August 2003
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **SUE THOMAS** Telephone No. (02) 6283 2454

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU02/00974

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed.

☒ the description, pages **2-9,** as originally filed,
pages , filed with the demand,
pages **1,** received on **21 July 2003** with the letter of **21 July 2003**

☒ the claims, pages **11-13** , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **10, 10a,** received on **21 July 2003** with the letter of **21 July 2003**

☒ the drawings, pages **1/7 - 7/7** , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages

☐ the claims, Nos.

☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- [ ] restricted the claims.
- [X] paid additional fees.
- [ ] paid additional fees under protest.
- [ ] neither restricted nor paid additional fees.

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- [ ] complied with.
- [X] not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-22 are directed towards a fluid pressure generating means for a heart assist device. It is considered that the housing defining an interior volume having a rigid first portion, a rigid second portion and a flexible third portion and an inlet/outlet port comprises a first "special technical feature".

2. Claims 23-30 are directed towards a heart assist device characterised by the shape and location of the device. It is considered that the housing having a fluid reservoir and fluid generating means that is so shaped as to lie in the pleural cavity comprises a second "special technical feature".

3. Claim 31 is directed towards a heart assist device characterised by a fluid generating means driven by an electric motor with sufficiently low cogging torque such that the natural systolic pressure is sufficient to cause liquid in the blood pumping means to return to the fluid reservoir in the event that the motor stops. It is considered that a mechanism for the patients circulatory system to cause liquid in the blood pumping means to return to the reservoir in the event that the electric motor stops comprises a third special technical feature.

(Continued in Supplemental Box)

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- [X] all parts.
- [ ] the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**1-31**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-31**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-31**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

Novelty (N) Claims 1-31

Claims 1-31 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose:

1. A fluid pressure generating means for a heart assist device comprising a housing filled with fluid and with a motor disposed within the interior volume of the housing.
2. A heart assist device including blood pumping means and fluid reservoir, the device shaped and dimensioned to lie in the pleural cavity.
3. A heart assist device including a fluid pressure generating means driven by an electric motor having a sufficiently low cogging torque such that the natural systolic pressure of the patient will cause the liquid to be returned to the fluid reservoir in the event the motor stops.

Inventive Step (IS) Claims 1-31

Claims 1-31 meet the criteria set out in PCT Article 33(3) with regard to the requirement of Inventive Step because the prior art does not obviously suggest to a person skilled in the art the inventions defined.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box IV

It is noted that the specification has admitted there are numerous systems for heart assist devices (page 1 lines 5 to 14) including an aortic compression means, a fluid reservoir, a means adapted to pump fluid from the reservoir to the aortic compression means in counter pulsation with the heart. Therefore a heart assist device with these said features cannot be considered to be special technical features in the present invention. When a claim does not avoid the prior art, its features cannot constitute "special technical features" for the purpose of assessing commonality of invention between claims. Refer to rule 13.2 of the PCT regulations for further explanation.

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, *a priori*.

A Fluid Pressure Generating Means

Field of the Invention

The present invention relates to a fluid pressure generating means for use with a heart assist device.

Background of the Invention

The applicant's international PCT patent application no. PCT/AU00/00654 (International publication no. WO 00/76288) entitled "Heart Assist Devices, Systems and Methods" ("the PCT application") discloses numerous embodiments of a novel heart assist device adapted for implantation into a patient. Broadly speaking, the disclosed heart assist devices include: an aortic compression means adapted, when actuated, to compress an aorta of a patient; a fluid reservoir; and a fluid pressure generating means adapted to pump fluid from the fluid reservoir to the aortic compression means so as to actuate the aortic compression means in counterpulsation with the patient's heart. The relevant portions of the PCT application are incorporated herein by cross-reference.

It is a first object of the present invention to provide improved fluid pressure generating means suitable for use with the aortic compression means described in the PCT application. It is a second object to provide a fluid pressure generating means which may be placed more conveniently into the body of a patient.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a fluid pressure generating means for a heart assist device having blood pumping means, the pressure generating means including:

a housing, defining an interior volume, and having a substantially rigid first housing portion, a substantially rigid second housing portion, a flexible third housing portion extending between the first and second housing portions and an inlet/outlet port adapted for fluid communication between the interior volume and the blood pumping means;

a fluid filling the housing; and

a motor or other actuator means disposed within the interior volume of the housing and connected between the first and second housing portions,

wherein actuation of the motor or other actuator means moves the first and second housing portions relative to one another to generate fluid pressure changes at the inlet/outlet port.

Claims:

1. A fluid pressure generating means for a heart assist device having blood pumping means, the pressure generating means including:

a housing, defining an interior volume, and having a substantially rigid first housing portion, a substantially rigid second housing portion, a flexible third housing portion extending between the first and second housing portions and an inlet/outlet port adapted for fluid communication between the interior volume and the blood pumping means;

a fluid filling the housing; and

a motor or other actuator means disposed within the interior volume of the housing and connected between the first and second housing portions,

wherein actuation of the motor or other actuator means moves the first and second housing portions relative to one another to generate fluid pressure changes at the inlet/outlet port.

2. The fluid pressure generating means as claimed in claim 1, wherein the third housing portion has an outer edge about its periphery and inner edge about an opening and is joined along the outer and the inner edge to the first and second housing portions respectively.

3. The fluid pressure generating means as claimed in claim 1, wherein the third housing portion is connected to only one of the first and second housing portions and abuts against the other of the first and second housing portions.

4. The fluid pressure generating means as claimed in claim 1, 2 or 3, wherein the blood pumping means is adapted to displace blood from the aorta of a patient in counter-pulsation with the patient's heart.

5. The fluid pressure generating means as claimed in claim 4, wherein the blood pumping means is adapted to displace blood from the ascending aorta of the patient.

6. The fluid pressure generating means as claimed in claim 1, 2 or 3, wherein the fluid pressure generating means is adapted to drive a conventional left ventricular assist device or an extra-ventricular co-pulsation heart compression device.

7. The fluid pressure generating means as claimed in any one of claims 1 to 5, wherein one of the first and second housing portions is moveable and the other of the first and second housing portions is fixed, the moveable housing portion being exposed to the outside of the heart assist device and adapted to interface with the lung of a patient.

8. The fluid pressure generating means as claimed in any one of claims 1 to 5, wherein one of the first and second housing portions is moveable and the other of the first